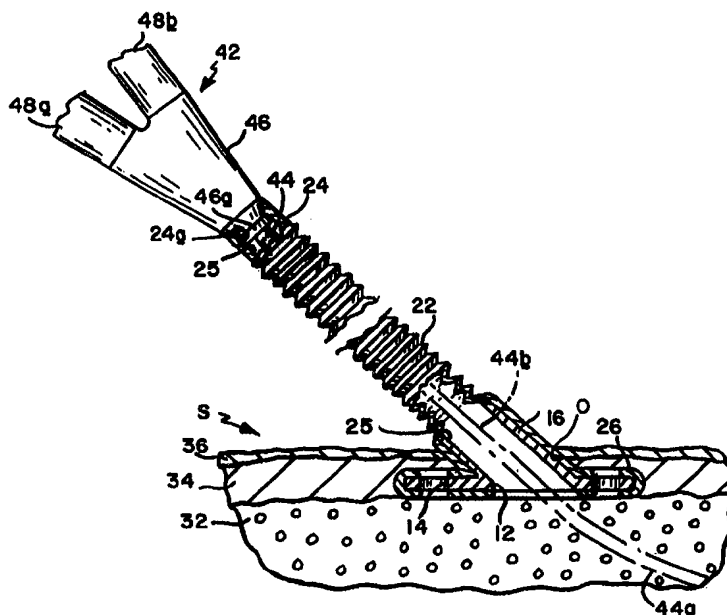




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: TRANSCUTANEOUS ACCESS DEVICE



(57) Abstract

A transcutaneous access device includes a subcutaneous skirt, a transcutaneous neck and an extracutaneous extensible sleeve all of which may be made of an inexpensive plastic material. Preferably, the skirt and neck are covered with a porous bed material which encourages the growth of tissue and collagen. The device functions as a conduit for an access catheter and is sized to minimize contact with the catheter and to allow vertical and horizontal motion of the catheter relative to the implanted portions of the access device so that twisting and stretching of the tissue adjacent to the implanted access device caused by normal body motions to not upset the biological seal that forms around the access device.

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TRANSCUTANEOUS ACCESS DEVICE

RELATED APPLICATION

This application is a continuation-in-part of Serial No. 08/499,543, filed
5 07/07/95.

FIELD OF THE INVENTION

This invention relates to a transcutaneous access device. It relates more particularly to a device of this type to facilitate access to the body through the
10 skin by catheters and similar percutaneous devices.

BACKGROUND OF THE INVENTION

There has of late been increasing use of catheters to provide prolonged or repeated access to the internal organs of chronically ill patients. For
15 example, catheters are used to access a patient's venous system for the administration of intravenous (IV) fluids, antibiotics, and chemotherapy. Catheters are also implanted in patients who require repeated access to the peritoneum for peritoneal dialysis.

Other than occlusion, the most common complications arising with long-
20 standing implants are exit-site infection, tunnel infection, local abscesses and even sepsis. Many of these complications arise because the skin adjacent to the catheter does not heal to form a tight barrier to infection. Rather, epidermal cells tend to invaginate or migrate inward along the catheter and never form a tight biological seal around the catheter. Also, tunnels are created through
25 which body fluids may exude thereby creating a site for infection.

In an attempt to overcome these problems, a catheter has been devised which includes a button-like skirt with a raised neck and a central hole for accommodating a tube. The tube has a corrugated segment extending above the button neck which allows the external portion of the tube to be flexed so as

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to absorb shocks. The skirt, including a portion of the neck thereof, is covered with a porous material, such as polyester velour, to allow for cell infiltration. When that device is implanted, the epidermal cells tend to migrate or invaginate downward along the neck to the skirt where they form a biological seal with the collagen and subcutaneous tissue growth on the porous covering of the button;
5 see patent 4,886,502.

While that concept was relatively successful in animals, it has had limited success in human trials because normal body motions caused stretching of the tissue adjacent to the catheter and exerted torsion on the catheter. Such
10 movements of the tissue relative to the button, which is held stationary by the external segment of the catheter tube, results in disruption of the biological seal between the catheter and the adjacent tissue. Such disruption may also occur when the external segment of the catheter tube is moved accidentally or intentionally when connecting and disconnecting the catheter tube to the
15 infusate source.

SUMMARY OF THE INVENTION

Accordingly, the present invention aims to provide a transcutaneous access device for a catheter which should circumvent most of the problems
20 caused by relative movement of the catheter and the tissue surrounding the catheter.

Another object of the invention is to provide a transcutaneous access device which, when implanted, provides a tight biological seal between the device and adjacent tissue.

25 A further object of the invention is to provide a device of this type which reduces the risk of infection;

Yet another object of the invention is to provide a transcutaneous access device which is relatively easy to manufacture in quantity.

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Other objects will, in part, be obvious and will, in part, appear hereinafter. The invention accordingly comprises the features of construction, combination of elements and arrangement of parts which will be exemplified in the following detailed description, and the scope of the invention will be indicated in the
5 claims.

The transcutaneous access device of this invention comprises a flat button with an opening therethrough and an integral upstanding tubular neck in registration with that opening. Formed as an integral extension of that neck is a flexible, extensible sleeve or tube whose free end is terminated by a collar which
10 is arranged to connect mechanically to a conventional access catheter that extends all the way through the lumen formed by the sleeve or tube, neck and button of the access device.

In accordance with the invention, the lumen of the present device is large enough to provide appreciable clearance between the walls of the lumen and the
15 access catheter so as to minimize contact between the access device and the access catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature and objects of the invention,
20 reference should be had to the following detailed description taken in connection with the accompanying drawings, in which:

FIG. 1 is an isometric view with parts broken away of a transcutaneous access device incorporating the invention;

FIG. 2 is a sectional view with parts in elevation showing the FIG. 1
25 access device implanted in the body and ready for use, and

FIG. 3 is a view similar to FIG. 1 of another embodiment of the access device.

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DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGS. 1 and 2 of the drawing, one embodiment of my access device comprises a flat, button-like main body or skirt 10 having a central opening 12 and an array of three to six through-holes 14 distributed around opening 12. Extending out from one side of skirt 10 in registration with opening 12 is an integral, tubular neck 16 whose lumen is in registration with opening 12. Skirt 10 and neck 16 should be stiff enough to maintain their shapes but be somewhat flexible and compliant so that when implanted they flex and "give" with the patient's dermis. In the illustrated device, the neck 16 extends out from skirt 10 at an angle; however, the neck could just as well be perpendicular to the skirt 10.

The device also includes a highly flexible, extensible tubular sleeve 22 extending from the free end of neck 16. In the FIGS. 1 and 2 device, sleeve 22 is a pleated accordion-like tube which forms a bellows and which is terminated at its free end by a cylindrical collar 24. Thus, the sleeve 22 allows the collar 24 to be moved toward and away from neck 16 in the order of 2-5 cm, as well as in all directions about the longitudinal axis of neck 16. The skirt 10, neck 16, sleeve 22 and collar 24 define a continuous, uniformly sized lumen 25 which extends through the entire device.

As best seen in FIG. 2, the collar 24 is formed with an internal lip 24a to provide a mechanical connection to an associated access catheter as will be described later.

The access device, including the skirt 10, neck 16, sleeve 22 and collar 24 are preferably formed of a flexible, thermally stable, biocompatible material such as flexible, medical grade polyurethane. The accordion-like sleeve 22 may be configured by placing a tubular extension of the neck 16 in a heated female mold and applying gas pressure inside the tube to force the tube walls to conform to the mold. The neck may then be secured to the button-like skirt 10 by welding. Alternatively, the device may be molded as a unitary part.

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Preferably, the entire surface of the body or skirt 10 is covered by a porous covering or bed 26 of a material such as medical grade polyester (Dacron) velour. Such a covered skirt 10 is available as Part No. 600K61121, from the U.S Catheter and Instrument Company of Glenfalls, New York. The
5 covering encourages cell infiltration and the formation of subcutaneous tissue and collagen and thus obtains a better bond than the PTFE material used in the above patent.

Typically, when the access device is used for peritoneal dialysis, the skirt 10 is in the order of 2.5 cm in diameter, the neck 16 is about 0.5 cm long,
10 the sleeve 22 is about 2 to 24 cm long and the diameter of the device's lumen 25 is in the order of 0.4 to 0.8 cm. On the other hand, when the device is used for vascular access, skirt 10 may be smaller, e.g., 1 cm in diameter, with the lengths of the neck and sleeve being 0.5 cm and 4 cm, respectively. In that event, the lumen 25 diameter may be in the order of 0.3 to 0.5 cm.

15 Referring to FIG. 2, the access device is implanted so that the skirt 10 is anchored in the subcutaneous tissue 32 and the covered neck 16 extends out through the dermal layer 34 and epidermal layer 36 of the skin S through an opening O. In time, tissue growth penetrates the through-holes 14 to help anchor the access device. Those same holes also allow for fluid drainage and
20 for sutures to anchor the device to tissue 32. As noted previously, the covering 26 provides a porous bed to encourage the growth of tissue and collagen around the body 10 to provide a biological seal with the epidermal cells which migrate or invaginate down around neck 16 until they reach the covering 26.

25 The access device is designed to be used in conjunction with an access catheter or catheter tube such as the one shown generally at 42 in FIG. 2. The illustrated catheter is a vascular access catheter. However, the catheter could just as well be a peritoneal access catheter. Suffice it to say that the catheter 42 includes a tube 44 which has an internal segment 44a which extends from the

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skin line along neck 16 and through body 10 to a selected infusion site such as the subclavian vein. The catheter tube also includes an external segment 44b which extends from the skin line through sleeve 22 and collar 24 to a Y-fitting 46 to which is connected a pair of fluid inlet tubes 48a and 48b so as to allow fluid from two different sources to be flowed to the catheter tube 44.

When the catheter 42 is properly seated in the access device, the lip 24a of the device's collar 24 is arranged to releasably engage over a radial flange 46a usually present at the lower end of the catheter fitting 46 to mechanically connect the catheter to the access device at the free end of the device's flexible sleeve 22. However, as noted previously, the device's lumen 25 is sized to minimize contact with the catheter tube 44 and so as not to inhibit motion of the catheter tube. Therefore, any motion of the internal catheter tube segment 44a caused by movements of the patient's body is substantially decoupled from the implanted portions of the access device, i.e., skirt 10 and neck 16. By the same token, if the external segment 44b of the catheter tube 44 should be moved accidentally or intentionally when connecting or disconnecting the catheter, the accordion-like sleeve 22 is able to flex, extend and contract as needed to accommodate such movement so that essentially no motion is coupled to the implanted portions of the access device. Resultantly, a tight biological seal is maintained between the access device and the surrounding tissue.

Indeed, actual experiments with prototype devices have shown that there are no signs of infection at the implantation sites even after the devices have been in place for prolonged periods.

Refer now to FIG. 3 which shows a second embodiment of my transcutaneous access device. It is similar to the FIG. 1 embodiment, except that its button-like skirt 50, tubular neck 52 and extensible sleeve 54 are formed as a unitary part. An annular connector member 56 which may be similar to member 24 is provided at the free end of the sleeve 54. Thus, the device has an

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axial passage or lumen 58 which extends the entire length of the device. A suitable material for the button-neck-sleeve unit is medical grade polyurethane sold under the designation Tecoflex EG 80A by Thermedics, Inc., Woburn, MA.

In this case, the extensible sleeve 52 is not accordion-like. Rather, it is a
5 thin-walled (e.g., 0.030 in.), elastic tube which can readily flex and extend lengthwise by the required amount, i.e., a few centimeters.

For most applications, sleeve 52 is more flexible and extensible than skirt 50 and neck 52. To achieve this result, the device is formed so that the skirt and neck have a greater wall thickness than the sleeve.

10 As in the FIG. 1 device, porous bed material is applied to exterior surfaces of the skirt 50 and neck 52. This material may be the same as or similar to the material used for bed 26 described above. Here, however, the material is applied in two parts. An annular piece 60a of bed material is slid onto the sleeve 54 and neck 52 and folded as shown in FIG. 3 so that it covers the
15 upper surface of the skirt and encircles the neck 52. It may be secured there by any suitable adhesive. To assure placement of the material piece 60a at the correct elevation on the neck 52 indicium 62 may be molded into or inscribed around neck 52.

Another annular piece 60b of bed material is adhered to the undersurface
20 of skirt 50, the opening through piece 60b being substantially the same size as lumen 58.

After being secured to skirt 50, the bed material pieces 60a and 60b may be trimmed so that their outer edges are even with the periphery of skirt 50.

The FIG. 3 embodiment of the device has all of the attributes of the FIG. 1
25 embodiment and functions in the same way described above in connection with the FIG. 1 embodiment.

As seen from the foregoing, my transcutaneous access device is, for the most part, a molded plastic part which can be made in quantity relatively easily

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and inexpensively. Therefore, it should find wide application wherever it is necessary to maintain catheters in situ for a long period of time.

In the course of testing my transcutaneous access device on human patients, I observed that when the device is removed after it has fulfilled its
5 function, there remains the small, e.g., 0.4 cm, opening O through the skin formerly occupied by the covered neck 16 (or 52).

Furthermore, the epidermal cells and connective tissue joined to the collagen growth encouraged by the covering 26 form a stable infection-free barrier or wall all around opening O. While that opening may normally be
10 closed by an appropriate skin graft. I have found that when left alone, the opening provides a permanent window through the skin to the subcutaneous tissue. It then occurred to me that this window could be used as a test site for an instrument that tests for diabetes or some other malady.

One instrument that tests for diabetes flashes ultraviolet or near
15 ultraviolet light on the skin and detects the reflected energy. From this, the instrument calculates the patient's blood sugar level. That information is then used to determine the correct insulin dosage for the patient at that time.

The test results from instruments of this type are adversely affected because the epidermis is a very good absorber of UV light. By providing a
20 permanent window through the skin to the subcutaneous tissue, the instrument can now illuminate that tissue directly and thus obtain a more accurate reading of the patient's sugar level.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since
25 certain changes may be made in the above construction without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawing shall be interpreted as illustrative and not in a limiting sense.

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It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention described herein.

CLAIMS

- 1 1. A transcutaneous access device comprising
2 a tubular neck having opposite ends and a lumen, said neck
3 adapted to protrude from the skin;
4 an annular skirt at one end of the neck for anchoring in
5 subcutaneous tissue;
6 a flexible, extensible sleeve extending from the opposite end of the
7 neck, said sleeve having a free end and defining with said neck a lumen
8 through the device;
9 a catheter tube received in said lumen and having opposite ends,
10 and
11 connector means releasably connecting the free end of the sleeve
12 to the catheter tube.

- 1 2. The device defined in claim 1 and further including a bed of porous
2 material substantially covering said skirt and at least a portion of said
3 neck.

- 1 3. The device defined in claim 1 wherein the porous material is polyester
2 velour.

- 1 4. The device defined in claim 1 and further including an array of through-
2 holes in said skirt.

- 1 5. The device defined in claim 1 wherein said skirt, neck and sleeve are of
2 flexible medical grade polyurethane.

- 1 6. The device defined in claim 1 wherein the connector means comprise
2 a first surface at the free end of said sleeve, and

3 a second surface on the catheter tube, said first and second
4 surfaces interfitting with each other so as to releasably connect the free
5 end of the sleeve to the catheter tube.

1 7. The device defined in claim 6 wherein said first surface is constituted by
2 a tubular collar at the free end of the sleeve, and
3 a circular lip formed on the inner surface of the collar to interfit with
4 the second surface.

1 8. The device defined in claim 1 wherein at least a segment of said sleeve is
2 accordion-like.

1 9. The device defined in claim 1 wherein at least a segment of said sleeve is
2 a thin-walled elastic tube.

1 10. The device defined in claim 9 wherein the skirt, neck and sleeve are
2 formed as a unit.

1 11. A transcutaneous access device comprising
2 a flat skirt having an opening therethrough;
3 a tubular neck extending from the skirt, said neck surrounding said
4 opening and having a flexible, extensible tubular extension, said opening,
5 said neck and said extension defining a lumen sized to receive the
6 catheter of an access catheter set with minimum contact between the
7 catheter and the walls of the lumen, and
8 connector means at the free end of said extension for mechanically
9 connecting the free end of the extension to the access catheter set.

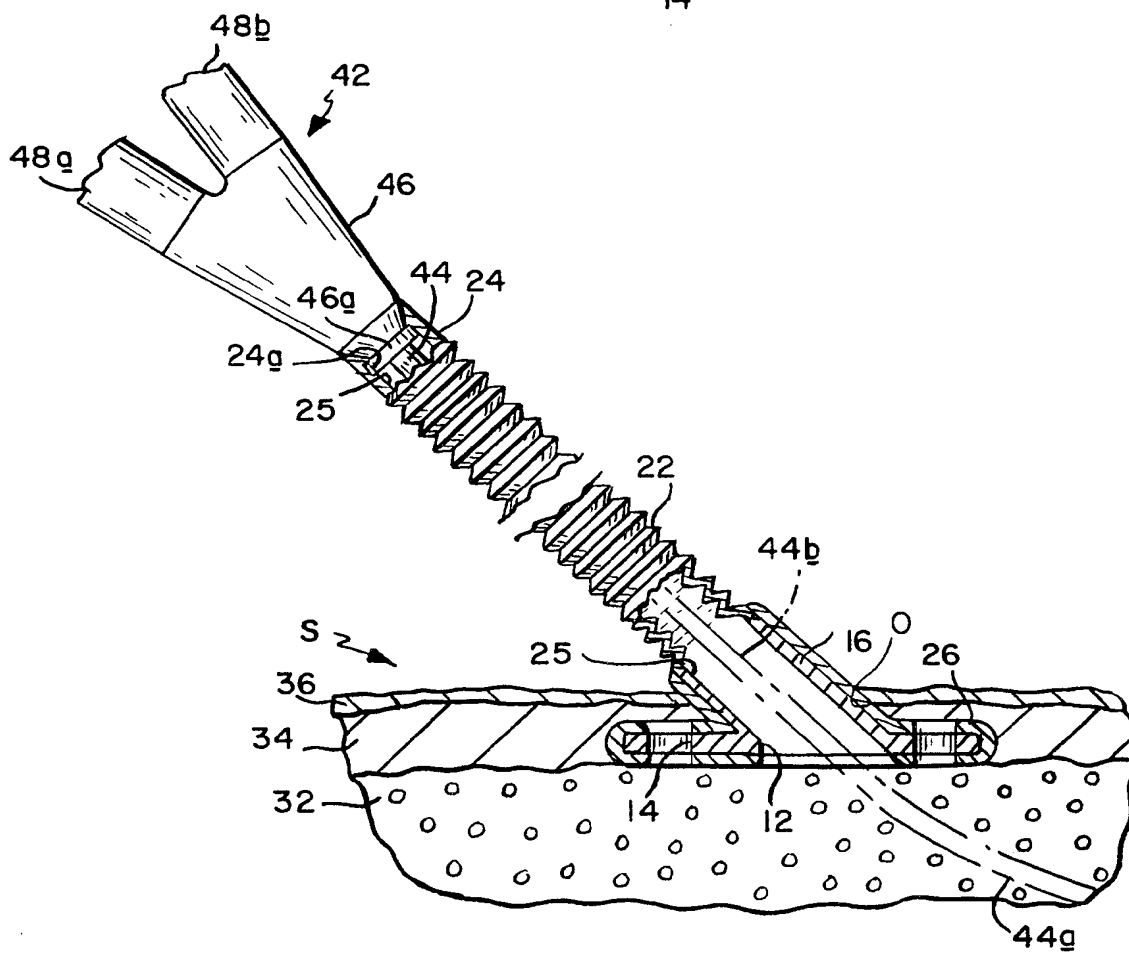
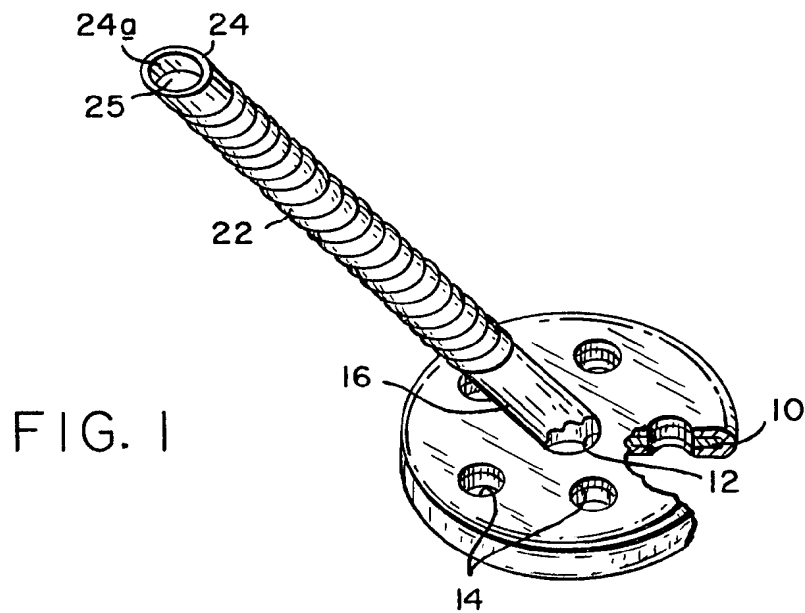
- 1 12. The device defined in claim 11 and further including a bed of porous
2 material substantially covering said button and at least a portion of said
3 neck.
- 1 13. The device defined in claim 11 wherein at least a segment of said
2 extension is accordion-like.
- 1 14. The device defined in claim 11 wherein at least a segment of said
2 extension is a thin-walled elastic tube.
- 1 15. A method of providing a long-lived window through the skin to
2 subcutaneous tissue comprising the steps of
3 forming a tubular body having an exterior surface of porous bed
4 material and opposite ends;
5 implanting the body so that one end of the body is below the
6 dermis and in contact with subcutaneous tissue and the opposite end is
7 extracutaneous;
8 leaving the body in situ until epidermal cells around the body
9 invaginate and migrate to the collagen that forms in the bed material to
10 provide a biological seal around the body, and
11 removing the body to expose a dermal hole within the seal.

AMENDED CLAIMS

[received by the International Bureau on 20 January 1998 (20.01.98);
original claims 1-14 cancelled; original claim 15 amended (1 page)]

- 1 15. A method of providing a long-lived window through the skin to
2 subcutaneous tissue comprising the steps of
3 forming a tubular body with a flexible skirt at one end of the
4 body, the other end of the body being free;
5 covering the exterior of the body with porous bed material;
6 in planting the body so that said skirt is below the dermis
7 and in contact with, but without penetration of, subcutaneous tissue
8 and the opposite end of the body is extracutaneous;
9 leaving the body in situ until epidermal cells around the body
10 invaginate and migrate to the collagen that forms in the bed material to
11 provide a biological seal around the body;
12 removing the body to expose a dermal hole within the seal, and
13 leaving the dermis around the hole unsutured so that the hole
14 constitutes said window.

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2/2

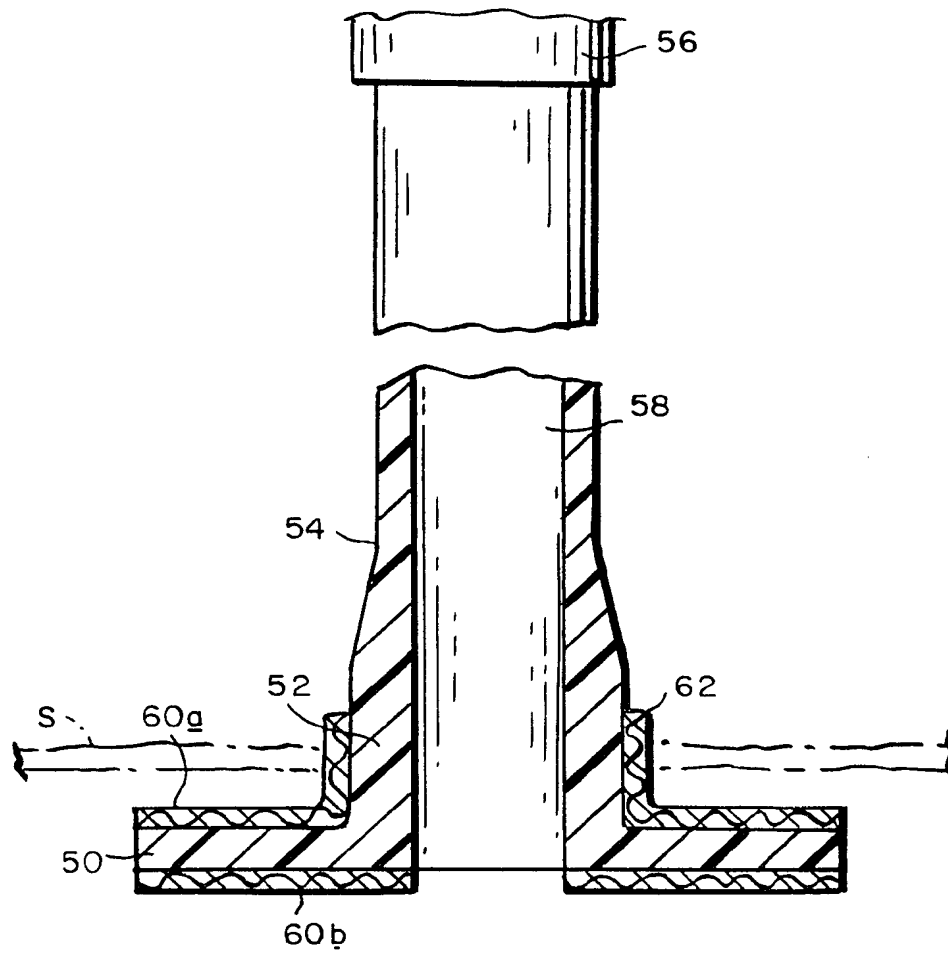


FIG. 3

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/14460

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 2 235 384 A (THERMEDICS INC.) 6 March 1991 see page 10, line 1 - page 13, line 22 see page 14, line 11 - line 21 see page 17, line 1 - page 18, line 6 see figures 6,7 ---	1-14
Y	US 5 073 166 A (PARKS ET AL.) 17 December 1991 see column 13, line 42 - column 14, line 9 see column 19, line 4 - line 11 see figures 8,9 ----	1-14
P, X	WO 97 02848 A (BOUSQUET) 30 January 1997 cited in the application see the whole document ----- -/--	1-14



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

17 November 1997

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

Inter. nal Application No

PCT/US 97/14460

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 886 502 A (POIRIER) 12 December 1989 cited in the application see column 3, line 11 - column 5, line 40 see figures 1-4 ---	1-5,8, 10-13
A	US 5 242 415 A (KANTROWITZ ET AL.) 7 September 1993 see column 3, line 4 - column 4, line 15 see figure 2 ---	1,11
A	US 4 402 694 A (ASH ET AL.) 6 September 1983 see column 3, line 49 - column 4, line 42 see figures 1,3 -----	1,11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 97/14460

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 15
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/US 97/14460

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2235384 A	06-03-91	FR 2651135 A US 5171216 A	01-03-91 15-12-92
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WO 9702848 A	30-01-97	US 5662616 A AU 6334196 A	02-09-97 10-02-97
US 4886502 A	12-12-89	NONE	
US 5242415 A	07-09-93	NONE	
US 4402694 A	06-09-83	NONE	